

## Claims

1. A method for preventing or treating male erectile dysfunction or female sexual arousal disorder, which method comprises administering to a mammal to whom such prevention or treatment is needed or desirable, an effective amount of
- a) vascular endothelial growth factor (VEGF) or a functional derivative or fragment thereof, or a nucleic acid encoding said VEGF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said VEGF, or
- b) brain-derived neurotrophic factor (BDNF) or a functional derivative or fragment thereof, or a nucleic acid encoding said BDNF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said BDNF, or
- c) basic fibroblast growth factor (bFGF) or a functional derivative or fragment thereof, or a nucleic acid encoding said bFGF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said bFGF,
- thereby preventing or treating said male erectile dysfunction or female sexual arousal disorder in said mammal.
2. The method of claim 1, wherein the mammal is a human and the VEGF, or a functional derivative or fragment thereof, or the nucleic acid encoding VEGF, or a functional derivative or fragment thereof, is of human origin.
3. The method of claim 1, wherein the mammal is a human and the BDNF, or a functional derivative or fragment thereof, or the nucleic acid encoding BDNF, or a functional derivative or fragment thereof, is of human origin.

4. The method of claim 1, wherein the mammal is a human and the bFGF, or a functional derivative or fragment thereof, or the nucleic acid encoding bFGF, or a functional derivative or fragment thereof, is of human origin.

5 5. The method of claim 1, wherein

a) the VEGF protein or nucleic acid, or a functional derivative or fragment thereof,

b) the BDNF protein or nucleic acid, or a functional derivative or fragment thereof, or

10 c) the bFGF protein or nucleic acid, or a functional derivative or fragment thereof,

is administered by intracavernous injection, subcutaneous injection, intravenous injection, intramuscular injection, intradermal injection, or topical administration.

15 6. The method of claim 1, wherein

a) the VEGF nucleic acid, or a functional derivative or fragment thereof,

b) the BDNF nucleic acid, or a functional derivative or fragment thereof, or

c) the bFGF nucleic acid, or a functional derivative or fragment thereof,

is administered via a gene therapy vector.

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7. The method of claim 6, wherein the gene therapy vector is selected from the group consisting of an adenovirus associated vector, a retroviral vector, an adenovirus vector, and a lentivirus vector.

25 8. The method of claim 6, wherein the gene therapy vector is an adenovirus associated vector.

9. The method of claim 1,

a) the VEGF protein, or a functional derivative or fragment thereof,  
b) the BDNF protein, or a functional derivative or fragment thereof, or  
c) the bFGF protein, or a functional derivative or fragment thereof,  
is administered via a liposome.

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10. The method of claim 1, wherein  
a) the VEGF nucleic acid, or a functional derivative or fragment thereof,  
b) the BDNF nucleic acid, or a functional derivative or fragment thereof, or  
c) the bFGF nucleic acid, or a functional derivative or fragment thereof,  
is administered via a liposome.

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11. The method of claim 1, wherein the male erectile dysfunction is erectile  
dysfunction induced by or secondary to nerve dysfunction, arterial insufficiency,  
venous leakage, hormonal insufficiency, drug use, surgery, chemotherapy or radiation.

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12. The method of claim 1, wherein the female sexual arousal disorder is sexual  
dysfunction induced by or secondary to nerve dysfunction, arterial insufficiency,  
hormonal insufficiency, drug use, surgery, chemotherapy, or radiation.

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13. The method of claim 1, wherein  
a) VEGF or a functional derivative or fragment thereof, or a nucleic acid  
encoding said VEGF or functional derivative or fragment thereof, or an agent that  
enhances production and/or said sexual arousal stimulating function of said VEGF, or  
b) BDNF or a functional derivative or fragment thereof, or a nucleic acid  
encoding said BDNF or functional derivative or fragment thereof, or an agent that  
enhances production and/or said sexual arousal stimulating function of said BDNF, or

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5 c) bFGF or a functional derivative or fragment thereof, or a nucleic acid encoding said bFGF or functional derivative or fragment thereof, or an agent that enhances production and/or said sexual arousal stimulating function of said bFGF, is administered in an amount sufficient to improve blood flow and regenerate nerve and smooth muscle in the clitoris and vaginal wall.

14. The method of claim 1, wherein

10 a) VEGF or a functional derivative or fragment thereof, or a nucleic acid encoding said VEGF or functional derivative or fragment thereof, or an agent that enhances production and/or said sexual arousal stimulating function of said VEGF, or

b) BDNF or a functional derivative or fragment thereof, or a nucleic acid encoding said BDNF or functional derivative or fragment thereof, or an agent that enhances production and/or said sexual arousal stimulating function of said BDNF, or

15 c) bFGF or a functional derivative or fragment thereof, or a nucleic acid encoding said bFGF or functional derivative or fragment thereof, or an agent that enhances production and/or said sexual arousal stimulating function of said bFGF, is administered in a cream or via injection to the clitoris and vaginal wall of the patient.

20 15. The method of claim 1, wherein

a) VEGF or a functional derivative or fragment thereof, or a nucleic acid encoding said VEGF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said VEGF, or

25 b) BDNF or a functional derivative or fragment thereof, or a nucleic acid encoding said BDNF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said BDNF, or

c) bFGF or a functional derivative or fragment thereof, or a nucleic acid encoding said bFGF or functional derivative or fragment thereof, or an agent that enhances production and/or said male erection or female sexual arousal stimulating function of said bFGF,  
5 is administered by intracavernous injection.

16. A combination for preventing or treating male erectile dysfunction or female sexual arousal disorder, which combination comprises:

a) an effective amount of an agent that stimulates male erectile or female sexual  
10 function; and

b) one or more of the following:

i) an effective amount of VEGF or a functional derivative or fragment thereof, or a nucleic acid encoding said VEGF or functional derivative or fragment thereof, or an agent that enhances the production and/or said erection or sexual  
15 arousal stimulating function of said VEGF;

ii) an effective amount of BDNF or a functional derivative or fragment thereof, or a nucleic acid encoding said BDNF or functional derivative or fragment thereof, or an agent that enhances production and/or said erection or sexual arousal stimulating function of said BDNF; or

20 iii) an effective amount of bFGF or a functional derivative or fragment thereof, or a nucleic acid encoding said bFGF or functional derivative or fragment thereof, or an agent that enhances production and/or said erection or sexual arousal stimulating function of said bFGF.

25 17. The combination of claim 16, wherein said combination is in the form of a pharmaceutical composition.

18. The combination of claim 16, which further comprises a pharmaceutically acceptable carrier or excipient.

19. A method for preventing or treating male erectile dysfunction or female sexual arousal disorder, which method comprises administering an effective amount of the combination of claim 16.

20. A kit, which kit comprises the combination of claim 16 and an instruction for using said combination in treating or preventing male erectile dysfunction or female sexual arousal disorder.

21. The method of claim 1, where the protein is administered at about 10-200 mcg/70 Kg body weight about once every two to six months.

22. The method of claim 6, wherein the gene therapy vector is administered by intracavernous injection of about 0.5 to 2 ml of AAV-VEGF, AAV-BDNF, or AAV-bFGF at a concentration of about  $10^{10}$  virus titer.